

The University of North Carolina at Chapel Hill
Consent for Storing Biological Samples Without Identifying Information

IRB Study # 99-EPA-285

Consent Form Version Date: March 20, 2006

Title of Study: "Physiological, Cellular, and Biochemical Effects of Diesel Exhaust in Healthy Young Adults"

Principal Investigator: Michael C. Madden

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Faculty Advisor: N/A

Funding Source: Internal US EPA funding

Study Contact telephone number:

Study Contact email:

What are some general things you should know about this research study?

Research studies are designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Research with blood, tissue and/or body fluids (specimens) can help researchers understand how the human body works. Research using specimens can also answer other questions. Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat diseases. In the future, some research may help to develop new products, such as drugs.

You may refuse to allow us to have or store your specimen. If you are a patient with an illness, you do not have to be in the research study in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The main purpose of this research study is to determine if a component of outdoors air pollution, diesel exhaust, causes inflammation in the lungs. Results from this study may increase the understanding of how gaseous and particulate air pollutants (which causes the haze seen in some polluted cities) may adversely affect the functioning of human lungs. This understanding may be especially important for patients with asthma or other cardiopulmonary diseases.

- Some or all of your collected specimens will be stored indefinitely in order to allow assays that may be developed in the future to better assess how you responded to a diesel exposure in terms of inflammation and other endpoints related to diesel exhaust toxicity.
- Your blood fluid and cells, lung fluid and cells, urine, and some breath components may be stored for research purposes. Although the primary purpose of collecting cells and fluids from your lung, blood, and other organ system is to determine whether your exposure to air pollutants might have affected them, occasionally there are cells and fluid left over. Rather than discard these cells, we may choose to use them for additional experiments in which they may be exposed to pollutants or other agents in the laboratory.
- The research studies in which the specimens may be used have not yet been determined.
- Your samples may possibly be analyzed in a way to be considered as genetic research but without your personal identifiers or links to your personal identifiers present; this research may indicate why you are or are not susceptible or sensitive to diesel exhaust as an example for use of your stored sample.

How will the specimen be collected?

- Briefly, and as more fully described in the consent form, blood will be drawn by standard venipuncture, urine via voluntary excretion, breath by exhaling into a chilled plastic tube or bag, and lung cells and fluid via bronchoscopy (ie, gentle brushing of your airways and also washing the airways with saline solution).

What will happen to the specimen?

- Samples will be stored in laboratories under the appropriate storage conditions. No personal identifiers will be provided on the samples. The PI and co-PIs will maintain records that link a sample code with your exposure type (i.e., air or diesel exhaust). The specimens may be shared with other institutions and research studies may be conducted at several locations at the same time.
 - The EPA Medical Station Staff will have access to your personal identifiers after the collection day.
 - Samples may be stored indefinitely.
- If it is deemed reasonable to release your specimen(s) to another researcher (not listed on the current protocol) in order to better meet the goals of this study, the PI may do so with no personal identifiers attached.

What are the possible benefits to you?

There will be no direct benefit to you for letting your specimen be stored for research. Research is designed to benefit society by gaining new knowledge. Future research with your specimen may provide additional information that will be helpful in identifying human responses to diesel exhaust inhalation and understanding factors that affect an individual's sensitivity to this pollutant. Society in general may benefit as more is learned about how air pollution irritates the airway and injures lungs.

What are the possible risks or discomforts involved with being in this study?

Briefly, and as more fully described in the consent, you may:

For the exposure days: you may breathe an unpleasant odor; have eye and nasal irritation;

experience headache, dizziness, and nausea. The risk of cancer, if it exists at all, is extremely low. You may have cough, shortness of breath, and chest discomfort.

For the bronchoscopy: there is a small chance that you will experience discomfort to the nose and throat, coughing, asthma-like attack, bleeding of the nose and airways, collapsed lung, confusion, lightheadedness, itching, tremors, euphoria, or seizures, low grade fever, pneumonia.

For venipuncture: some pain and a possible bruise may occur to you.

In addition, there may be uncommon or previously unrecognized risks that might occur. You should report any problems to the researchers.

Will there be any cost to you for storage of the specimens?

There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for being in this study?

You will receive monetary compensation for their time and participation at each stage of the study, including recruitment. A total of \$15 will be paid to you for completing office visit with recruitment, and \$15 for the physical examination (including blood work). A fee of \$20 will be paid for the bronchoscopy physical. \$5 will be paid for completing each symptom questionnaire. Payment of \$325 applies to each bronchoalveolar lavage procedure (including a blood sample). \$38 will be paid for each of the brush biopsy procedure. You are paid \$12/hour for their time. \$100 will be paid for 24 hr of Holter monitoring. \$20 will be paid for each lung function test and \$20 for each airways resistance test. \$5 and \$15 will be paid for each gaseous breath and breath condensate collections, respectively. A subject who is unable to complete the bronchoscopy procedure for voluntary or involuntary reasons will receive full compensation for his/her participation to that point, including the bronchoscopy.

You will also receive \$25 for each blood draw and \$ 10 for providing each urine specimen. A completion bonus of \$50.00 will be awarded if you participate in the entire study. You will be reimbursed for lunch (\$5) on Day 1 of each exposure. Overall you will be paid approximately \$1996 for their complete participation in this study. All parking costs will also be paid. Out of town, i.e., outside Carrboro and Chapel Hill, travel costs will be reimbursed at US government travel rates. Thus you will bear no costs for participation in the project.

Who owns the specimens?

Any blood, body fluids, or tissue specimens obtained for the purpose of this study become the exclusive property of the US EPA. The researchers may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will your privacy be protected?

The researchers will not have any identifying information about you so there is no risk to your privacy.

Will you receive study results of future research involving your specimens?

You will not receive study results of future research because the researchers have no information that identifies you.

Can you withdraw the specimen from this repository?

You may not withdraw your specimen in the future because there are no identifiers on the specimen and the researchers will not know which specimen is yours.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company.

Neither the University of North Carolina at Chapel Hill nor the U.S. EPA has set aside funds to pay you for any such reactions or injuries, or for the related medical care. If you believe you have suffered a research-related injury, you have the right to pursue legal remedy if you believe that your injury justifies such action. The Federal Tort Claims Act, 28 U.S.C. S 2671 et seq., provides for money damages against the United States when property loss or personal injury results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence. If a research-related injury occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6217.

Who is sponsoring this study?

This research is funded by the United States Environmental Protection Agency (US EPA). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. The PI is employed as a research biologist by the U.S. EPA, the sponsor of this research, and as such collect salary and possible awards from the Agency.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously, if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Principal Investigator: Michael C. Madden

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored without any identifying code(s).

Signature of Research Subject

Date

Printed Name of Research Subject

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent